MAR 1 5 2006

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HemiCAP™ Patello-Femoral Resurfacing Prosthesis

510(K) Summary
Of Safety and Effectiveness

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this information serves as a Summary of Safety and Effectiveness for the HemiCAP™ Patello-Femoral Resurfacing Prosthesis.

Submitted By:	Arthrosurface, Inc. 28 Forge Parkway Franklin, MA 02038 (508) 520-3003
Date:	16 January 2006
Contact Person:	Steven W. Ek Chief Operations Officer
Proprietary Name:	HemiCAP™ Patello-Femoral Resurfacing Prosthesis
Common Name:	Knee Joint Patellofemoral polymer/metal semi-constrained cemented prosthesis
Classification Name:	Knee Joint Patello-femoral Resurfacing Prosthesis Orthopedic 21 CFR § 888.3540 (2003) Class II
Product Code:	KRR
Indications for Use:	The HemiCAP™ Patello-femoral Resurfacing Prosthesis is intended to be used in cemented arthroplasty in patients with osteoarthritis limited to the distal patello-femoral joint, patients with a history of patellar dislocation or patellar fracture, and those patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release, etc.) where pain, deformity or dysfunction persists.

Device Description:

The HemiCAP™ Patello-Femoral Resurfacing Prosthesis incorporates a distal femoral trochlear surface articular component that mates to a fixation stud via a taper interlock, and an all-polyethylene patella component. The prosthesis is intended to be used in cemented arthroplasty.

The femoral articular component is manufactured of a Cobalt-Chromium-Molybdenum alloy per ASTM F799 and ASTM F1537. The component has a bone contact surface that is coated with a spray-applied CP Titanium coating and a polished articular bearing surface. The fixation stud component is a short tapered cylinder, 13mm in length, manufactured of a Ti-6Al-4V ELI alloy per ASTM F136. The stud has a tapering helix, a full-length cannulation, and a proximal female taper bore. The patella prosthesis component is comprised of ultra-high-molecular weight polyethylene (UHMWPE) manufactured and tested to meet standards specified in ASTM F 648-04, Type I. The materials, manufacturing methods, and surface finish requirements for these components are identical to those used for the Sponsor's previously cleared devices (K021549, K023096, K031859, K050373).

Performance Testing:

Non-Clinical Performance Testing completed as part of the Arthrosurface Design Control Procedure has demonstrated that the device is safe and effective and substantially equivalent to the predicate devices.

Clinical data was not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 15 2006

Arthrosurface, Incorporated
c/o Mr. Steven W. Ek
Chief Operations Officer
28 Forge Parkway
Franklin, Massachusetts 02038

Re: K060127
Trade/Device Name: HemiCAP™ Patello-Femoral Resurfacing Prosthesis
Regulation Number: 21 CFR 888.3540
Regulation Name: Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: KRR
Dated: January 16, 2006
Received: January 24, 2006

Dear Mr. Ek:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

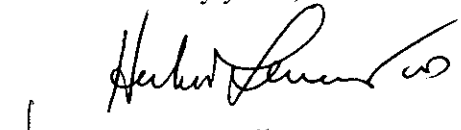
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060127

Device Name: HemiCAP™ Patello-Femoral Resurfacing Prosthesis

Indications for Use:

The HemiCAP™ Patello-femoral Resurfacing Prosthesis is intended to be used in cemented arthroplasty in patients with osteoarthritis limited to the distal patello-femoral joint, patients with a history of patellar dislocation or patellar fracture, and those patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release, etc.) where pain, deformity or dysfunction persists.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___No___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K060127

(Posted November 13, 2003)